

In the Supreme Court of the United States

OCTOBER TERM, 1979

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, PETITIONER

v.

MALCOLM E. BERGY, ET AL.

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, PETITIONER

v.

ANANDA M. CHAKRABARTY

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEALS

BRIEF FOR THE PETITIONER

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Cases—Continued	II	Page
<i>Allen v. Grand Central Aircraft Co.</i> , 347 U.S. 535		28
<i>American Cyanamid Company (Dann's) Patent</i> , 1971 Pat. Cas. 425		40
<i>Arzberger, In re</i> , 112 F.2d 834	17, 27-28	
<i>Born v. Allen</i> , 291 F.2d 345		23
<i>Califano v. Sanders</i> , 430 U.S. 99		30
<i>Cameron Septic Tank Co. v. Village of Saratoga</i> , 159 F. 453, cert. denied, 209 U.S. 548		37
<i>The Corn-Planter Patent</i> , 23 Wall (90 U.S.), 181		32
<i>Dann v. Johnston</i> , 425 U.S. 219		2
<i>Deepsouth Packing Company v. Laitram</i> , 406 U.S. 518		12
<i>Deutsch, Application of</i> , 553 F.2d 689.....		38
<i>Dick v. Lederle Antitoxin Laboratories</i> , 43 F.2d 628		37
<i>Douglas v. Seacoast Products, Inc.</i> , 431 U.S. 265		35
<i>Fishgold v. Sullivan Drydock & Repair Corp.</i> , 328 U.S. 275		39
<i>Fourco Glass Co. v. Transmirra Corp.</i> , 353 U.S. 222		23
<i>Gottschalk v. Benson</i> , 409 U.S. 63		2
<i>Graham v. John Deere Company</i> , 383 U.S. 1		12
<i>Guaranty Trust Company v. Union Solvents Corporation</i> , 54 F.2d 400, aff'd, 61 F.2d 1041, cert. denied, 288 U.S. 614	13, 38	
<i>Helvering v. Hallock</i> , 309 U.S. 106		40
<i>Johnson v. Southern Pacific Co.</i> , 196 U.S. 1		25
<i>Larsen, Application of</i> , 292 F.2d 531.....		40

Cases—Continued	III	Page
<i>Latimer, Ex Parte</i> , 1889 Dec. Comm. Pat. 123		35, 36
<i>Le Grice, Application of</i> , 301 F.2d 929		24
<i>Mackay Radio & Telegraph Co. v. Radio Corp. of America</i> , 306 U.S. 86		38
<i>Marcy, Application of</i> , 499 F.2d 1289	13, 14	
<i>Merat, Application of</i> , 519 F.2d 1390		14
<i>New York Central R.R. v. Winfield</i> , 244 U.S. 147		25
<i>NLRB v. Bell Aerospace Co.</i> , 416 U.S. 267		30
<i>Northcross v. Memphis Board of Education</i> , 412 U.S. 427		28
<i>Parker v. Flook</i> , 437 U.S. 584....8, 9, 12, 21, 23, 38		
<i>Platt v. Union Pacific R.R.</i> , 99 U.S. 48.....		23
<i>Red Lion Broadcasting Co. v. FCC</i> , 395 U.S. 367		30
<i>Sears, Roebuck & Company v. Stiffel Company</i> , 376 U.S. 225		12
<i>SEC v. Sterling Precision Corp.</i> , 393 F.2d 214		39
<i>Stonite Products Co. v. Melvin Lloyd Co.</i> , 315 U.S. 561		23
<i>Toma, Application of</i> , 575 F.2d 872		38
<i>Udall v. Tallman</i> , 380 U.S. 1		40
<i>United States v. Price</i> , 361 U.S. 304		30
<i>United States v. Ruzicka</i> , 329 U.S. 287....		23
<i>United States v. Silk</i> , 331 U.S. 704		25
<i>Waldbaum, Application of</i> , 559 F.2d 611..		38
<i>Yoder Bros., Inc. v. California-Florida Plant Corp.</i> , 537 F.2d 1347, cert. denied, 429 U.S. 1094		16
<i>Zuber v. Allen</i> , 396 U.S. 168		40

IV

Statutes:

Page

Plant Patent Act of 1930, 35 U.S.C. 161 <i>et seq.</i>	5, 11, 16, 31
35 U.S.C. 161-164	21
35 U.S.C. 161	3, 17
35 U.S.C. 162	16, 36
35 U.S.C. 163	16
35 U.S.C. 171	23
35 U.S.C. 271	23
Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542, 7 U.S.C. 2321 <i>et seq.</i>	3, 11, 16, 27
7 U.S.C. 2401	17
7 U.S.C. 2402	10, 17, 27
7 U.S.C. 2402(a)	3, 22
7 U.S.C. 2404	16
7 U.S.C. 2421	27
7 U.S.C. 2422	16
7 U.S.C. 2483(c)	16
7 U.S.C. 2541	23
7 U.S.C. 2543	16
7 U.S.C. 2544	16
Rev. Stat. 4886	5, 22, 31, 37
Rev. Stat. 4888	36, 37
35 U.S.C. 101	<i>passim</i>
35 U.S.C. 112	36

Congressional materials:

72 Cong. Rec. 8391 (1930)	26
72 Cong. Rec. 8392 (1930)	32
116 Cong. Rec. 34680 (1970)	29
116 Cong. Rec. 40295 (1970)	29
Hearings on H.R. 11372 Before the House Comm. on Patents, 71st Cong., 2d Sess. (1930)	26, 35, 37

V

Congressional materials—Continued

Page

Patent Law Revision: Hearings on S. 2, S. 1042, S. 1377, S. 1691, S. 2164, S. 2597, Before the Subcomm. on Pat- ents, Trademarks and Copyrights of the Senate Comm. on the Judiciary, Part 2, 90th Cong., 2d Sess. (1968)	15
Plant Variety Protection: Hearings on H.R. 13424, etc., Before the Subcomm. on Departmental Operations of the House Comm. on Agriculture, 91st Cong., 2d Sess. (1970)	29
Plant Variety Protection Act: Hearings on S. 3070 Before the Subcomm. on Agricultural Research and General Leg- islation of the Senate Comm. on Agri- culture and Forestry, 91st Cong., 2d Sess. (1970)	29
H.R. 9765, 71st Cong., 2d Sess. (1930)....	35
H.R. Rep. No. 1129, 71st Cong., 2d Sess. (1930)	24, 25, 27, 32, 34, 37
H.R. Rep. No. 91-1605, 91st Cong., 2d Sess. (1970)	28
S. 3530, 71st Cong., 2d Sess. (1930).....	35
S. Rep. No. 315, 71st Cong., 2d Sess. (1930)	24, 25, 27, 32, 34, 37
S. Rep. No. 91-1246, 91st Cong., 2d Sess. (1970)	28, 29

Miscellaneous:

ABA Patent, Trademark and Copyright Law Section, 1966 <i>Summary of Proceed- ings</i> (1967)	14
ABA Patent, Trademark and Copyright Law Section, 1969 <i>Committee Reports</i> (1970)	14

Miscellaneous—Continued	Page
ABA Patent, Trademark and Copyright Law Section, <i>1976 Committee Reports</i> (1977)	14
ABA Patent, Trademark and Copyright Law Section, <i>1976 Summary of Proceedings</i> (1977)	15
R. Allyn, <i>The First Plant Patents</i> (1934) ..	16, 35
Blakeslee and Avery, <i>Methods of Inducing Doubling of Chromosomes in Plants</i> , 28 J. of Heredity (1937)	34
<i>Chemical Week</i> 34 (Sept. 26, 1979)	19
Commissioner of Patents and Trademarks, <i>Annual Report FY 1978</i> (1979)	39
H. de Vries, <i>Plant Breeding</i> (1907)	33, 34
Diенner, <i>Patents for Biological Specimens and Products</i> , 35 J. Pat. Off. Soc'y 286 (1953)	15, 26
Emsweller, <i>Use of Colchicine in Plant Breeding</i> , in <i>Brooklyn Botanic Garden, Handbook on Breeding Ornamental Plants</i> (1959)	33
Fairchild, <i>The Fascination of Making a Plant Hybrid</i> , 18 J. of Heredity (1927) ..	32
41 Fed. Reg. 27902-27941 (1976)	18
41 Fed. Reg. 27903-27904 (1976)	18
41 Fed. Reg. 27902 (1976)	19
41 Fed. Reg. 27904 (1976)	19
42 Fed. Reg. 2712-2713 (1977)	20
42 Fed. Reg. 13147 (1977)	20
43 Fed. Reg. 60080, 60108, 60134 (1978) ..	20
44 Fed. Reg. 63074, 63075 (1979)	19
Federico, <i>Louis Pasteur's Patents</i> , 86 Science 327 (1937)	40

Miscellaneous—Continued	Page
Glascoek and Stringham, <i>Patent Soliciting and Examining</i> (1934)	16
Gore, <i>The Awesome Worlds Within a Cell</i> , 150 Nat'l Geographic (Sept. 1976)	39
W. S. Harwood, <i>New Creations in Plant Life</i> (1905)	33
J. James, <i>Create New Flowers and Plants Indoors and Out</i> (1964)	33
Jeffrey, <i>The Patentability and Infringement of Sport Varieties: Chaos or Clarity?</i> , 59 J. Pat. Off. Soc'y 645 (1977)	16
D. Jordan & V. Kellogg, <i>The Scientific Aspects of Luther Burbank's Work</i> (1909)	33
Mole, <i>The Expanding Scientific Role of the Federal Government in the Nineteenth Century: The Patent Office as a Case Study</i> , 60 J. Pat. Off. Soc'y 328 (1978) ..	32
1 Recombinant DNA Research, <i>Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules," February 1975-June 1976</i> , DHEW Pub. No. (NIH) 76-1128 (National Institutes of Health, Public Health Service, 1976)	18, 19
2 Recombinant DNA Research, <i>Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules," June 1976-November 1977</i> , DHEW Pub. No. (NIH) 78-1139 (National Institutes of Health, Public Health Service, 1978)	20

VIII

Miscellaneous—Continued	Page
Rossmann, <i>The Preparation and Prosecution of Plant Patent Applications</i> , 17 J. Pat. Off. Soc'y 632 (1935)	15
Singleton, <i>et al.</i> , <i>Radiation Genetics and Crop Improvement</i> in Brooklyn Botanic Garden, <i>Handbook on Breeding Ornamental Plants</i> (1959)	33, 34
Thorne, <i>Relation of Patent Law to Natural Products</i> , 6 J. Pat. Off. Soc'y 23 (1923)	23, 36
Wade, <i>Major Relaxation on DNA Rules</i> , 205 Science 1238 (1979)	20
Wade, <i>Recombinant DNA: Warming up for Big Payoff</i> , 206 Science 663 (1979) ..	18
Weaver, <i>The Cancer Puzzle</i> , 150 Nat'l Geographic 396 (Sept. 1976)	39

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OPINIONS BELOW

The most recent opinion of the Court of Customs and Patent Appeals (Pet. App. A, 1a-103a) in these cases is reported at 596 F.2d 952.

(1)

The order of this Court remanding *Parker v. Bergy* to the Court of Customs and Patent Appeals is reported at 438 U.S. 902. The prior opinion of the Court of Customs and Patent Appeals in that case (Pet. App. C, 106a-128a) is reported at 563 F.2d 1031. The opinion of the Patent and Trademark Office Board of Appeals (Pet. App. D, 129a-139a) is reported at 197 U.S.P.Q. 78. The opinion of the patent examiner (Pet. App. E, 140a-141a) is not reported.

The prior opinion of the Court of Customs and Patent Appeals in the second case, *Application of Chakrabarty* (Pet. App. F, 142a-158a) is reported at 571 F.2d 40. The opinions of the Patent and Trademark Office Board of Appeals (Pet. App. G, 159a-164a; Pet. App. I, 168-169a) and of the patent examiner (Pet. App. H, 165a-167a) in that case are not reported.

JURISDICTION

The judgments of the Court of Customs and Patent Appeals were entered on March 29, 1979 (Pet. App. B, 104a-105a). On June 13, 1979, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including July 27, 1979. The petition was filed on that date, and granted on October 29, 1979. The jurisdiction of this Court rests on 28 U.S.C. 1256. *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Dann v. Johnston*, 425 U.S. 219 (1976).

QUESTION PRESENTED

Whether a living organism is patentable subject matter under 35 U.S.C. 101.

STATUTES INVOLVED

35 U.S.C. 101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Plant Patent Act of 1930, 35 U.S.C. 161, provides in relevant part:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor * * *.

Section 42(a) of the Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1547, 7 U.S.C. 2402(a), provides in relevant part:

The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor * * *.

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STATEMENT

A. Bergy

In 1974, Malcolm E. Bergy and two other scientists applied for a patent (A. 4-26), assigned to the Upjohn Company (Pet. App. 4a), with four claims to a process for preparing the antibiotic lincomycin using a newly isolated microorganism, *Streptomyces vellosus* ("S. vellosus") (A. 22)¹ and a fifth claim for a culture of *S. vellosus* itself, as follows (A. 25):

A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

The examiner allowed claims 1-4 (the process claims), and his decision on those claims is not in dispute (Pet. App. 27a, 140a). He rejected claim 5, however, on the basis that *S. vellosus* is a product of nature and thus not patentable (Pet. App. 140a).

The Board of Appeals, with one member dissenting, sustained the rejection of claim 5 on the ground that a living organism is not patentable subject matter under 35 U.S.C. 101 (Pet. App. 129a-139a).

¹ This microorganism was found in Arizona soil samples (A. 6, 9) and a subculture, supplied by Upjohn, is permanently maintained by the Department of Agriculture at its research facilities. It is identified by its accession number, NRRL 8037 (A. 6).

The Board found support for this view in the Plant Patent Act of 1930, 35 U.S.C. 161 *et seq.* It reasoned that Congress would not have specifically given patent protection under the 1930 Act to certain kinds of plants if it had believed that patents could already be obtained for these plants, as living organisms, under the general patent laws, Rev. Stat. 4886, now 35 U.S.C. 101 (Pet. App. 130a-132a).²

The Court of Customs and Patent Appeals reversed, with two judges dissenting (Pet. App. 106a-128a). The court reasoned that, since patents are available for processes using a strain of living bacteria (*e.g.*, in septic systems or to produce alcohol), it would be "illogical" to insist that the living bacteria in a biologically pure culture are not themselves statutory subject matter (Pet. App. 118a).

On June 26, 1978, this Court granted a petition for a writ of certiorari filed by the Solicitor General seeking review of the Court of Customs and Patent Appeals' decision, vacated the judgment and remanded the case to the Court of Customs and Patent Appeals "for further consideration in light of *Parker v. Flook*, 437 U.S. 584" (438 U.S. 902).

B. Chakrabarty

On June 7, 1972, Ananda Chakrabarty filed a patent application (A. 40-84), assigned to the General

² It did not reach the "product of nature" issue upon which the examiner's decision rested. The dissenting Board member concluded that claim 5 involved a "composition" or "manufacture" and was accordingly patentable under 35 U.S.C. 101 (Pet. App. 132a).

Electric Company, with 36 claims to, *inter alia*, a strain of bacteria from the genus *Pseudomonas*, and an inoculum consisting essentially of these bacteria (A. 72-74). Certain strains of *Pseudomonas* bacteria existing in nature are capable of degrading by enzymatic reactions a particular component of a complex hydrocarbon, such as crude oil, but no known naturally-occurring bacterium can degrade more than one such component. Chakrabarty employed so-called "genetic engineering" to develop a *Pseudomonas* bacterium capable of degrading more than one component of crude oil (Pet. App. 142a-143a).³

Although the examiner allowed claims for the process by which incompatible plasmids present in a *Pseudomonas* bacterium are fused to render them compatible,⁴ he rejected the claims for the genetically engineered *Pseudomonas* bacteria themselves, apparently on two grounds: (1) the microorganisms are

³ Plasmids, which are hereditary units separate from the chromosomes, carry the hydrocarbon-degrading capacity of the cell. Chakrabarty utilized a process of natural conjugation (A. 41, 46) to effectuate the transfer to a single cell of plasmids from various known strains of bacteria, each known to have a specific capacity to degrade a particular component of crude oil (A. 46-50). The resulting organism, which Chakrabarty seeks to patent, is a bacterium with increased hydrocarbon-degrading capacities due to the different kinds of plasmids it contains (Pet. App. 143a).

⁴ The examiner also allowed claims 30-32 and 35-36, which were for an inoculum comprised of a carrier material able to float on water and of *Pseudomonas* bacteria containing at least two plasmids, each providing a separate hydrocarbon-degrading pathway (A. 88).

"products of nature"; and (2) as living organisms they are not patentable subject matter under 35 U.S.C. 101 (Pet. App. 165a-167a; A. 87).

The Board of Appeals affirmed the examiner on the second ground (Pet. App. 160a-163a).⁵ Relying on the legislative history of the Plant Patent Act, the Board reasoned that the terms "manufacture" or "composition of matter" in 35 U.S.C. 101 were not intended to cover living organisms (Pet. App. 161a-162a). The Board also observed that if 35 U.S.C. 101 were interpreted to encompass genetically-modified bacteria, it could also be read to encompass modified living multicellular organisms (*ibid.*).

The Court of Customs and Patent Appeals reversed, with two judges again dissenting (Pet. App. 142a-158a). The majority found the case indistinguishable from *Bergy* (Pet. App. 147a-148a).

On July 26, 1978, the Solicitor General filed a petition for a writ of certiorari seeking review of the Court of Customs and Patent Appeals' decision (No. 78-145). Shortly thereafter, however, that court vacated its earlier judgment, recalled its mandate and restored the appeal to the calendar. On August 25, 1978, pursuant to the parties' stipulation, the petition for a writ of certiorari was dismissed (Pet. App. 5a-6a).

⁵ The Board rejected the product-of-nature theory partially relied upon by the examiner, noting that *Pseudomonas* bacteria containing two or more hydrocarbon-degrading plasmids are not naturally occurring (Pet. App. 163a).

C. The Decision After Remand

The Court of Customs and Patent Appeals reaffirmed its earlier judgments in both cases (Pet. App. 40a, 70a).⁶ The majority discussed *Parker v. Flook*, 437 U.S. 584 (1978), which it distinguished as being “concerned only with the question of what is a ‘process’ under § 101”, an issue unrelated to the appeals before it (Pet. App. 22a). It found the holding in *Flook*—that an improved method of calculation is unpatentable under Section 101—similarly inapplicable (*id.* at 22a). Stressing that there was “no formula, algorithm, or law of nature” involved here (Pet. App. 23a), the Court of Customs and Patent Appeals summarized: “[t]o conclude on the light *Flook* sheds on these cases, very simply * * * we find none” (*id.* at 26a).⁷ It therefore adhered both to the analysis and the conclusion in its earlier decisions, emphasizing that the plain language of Section 101 does not distinguish between living and inanimate matter (*id.* at 44a-45a, 64a-65a, 69a), and that microorganisms should be treated no differently under Section 101 than chemical compounds (*id.* at 45a).⁸

⁶ The court, though not formally consolidating the cases, heard and decided them together because they involved “the same single question of law” (Pet. App. 2a).

⁷ It nevertheless asserted that *Flook* contained “an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated” (Pet. App. 10a), and adopted a “novel * * * doctrine” with “potential for great harm to the incentives of the patent system” (*id.* at 23a-24a).

⁸ In a separate concurrence, Judge Baldwin found that the precedents cited in *Parker v. Flook* defined an area where

Judge Miller, dissenting, stated that the majority had read *Parker v. Flook*, *supra*, too narrowly. He interpreted the decision in *Flook* as requiring a clear and certain signal from Congress where there is substantial doubt that Congress intended to include a particular development as patentable subject matter under Section 101. From his reading of the legislative history of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, Judge Miller found at least a substantial doubt about Congress’ intent to include living things within the scope of patentable subject matter in Section 101 (Pet. App. 96a). Accordingly, in the absence of any clear and certain signal that they were to be included, the courts should not bring them within the bounds of Section 101 by unwarranted judicial construction of the statutory language (*ibid.*).

SUMMARY OF ARGUMENT

Under this Court’s decisions, the patent laws are to be strictly construed in light of the basic national economic policy against monopoly, and in order to reserve to Congress decisions concerning extension of the patent laws into new areas. Congress, rather

patents were not possible because “the inventor attempted to preclude others from using those bare [natural] phenomena” (Pet. App. 88a). He observed that in the instant cases the inventions did not “reach out to encompass natural phenomena * * *, but rather recite only non-naturally occurring compositions of matter that are but single tools for utilizing natural phenomena in producing new and useful end results” (Pet. App. 91a).

than the judiciary, is empowered and is best able to resolve the complex social, economic, and scientific questions frequently involved in such decisions, and, if an extension is to be made, to tailor the statute to achieve precisely the desired ends. The determination whether living organisms produced by "genetic engineering" of the kind involved in Chakrabarty's invention should themselves be patentable is just such a decision. It involves social, economic and scientific questions of great complexity. Moreover, if Congress should decide to extend patent protection to such inventions, it might well decide to do so by a specifically tailored statute, similar to those it has provided for certain hybridized plants, rather than by providing generally for the patentability of living organisms under the basic patent law.

Congress has not yet made that determination. Indeed, the only specific reference to bacteria in the relevant statutes provides that they are *not* to receive patent-type protection (7 U.S.C. 2402). Until the instant cases, it was generally assumed by the legal profession, writers on the subject, and Congress, that the patent law's provision (35 U.S.C. 101) for the patentability of a new and useful "manufacture, or composition of matter" did not permit the patenting of living organisms.⁹ Congress acted on this assump-

⁹ The Commissioner and the Board of Appeals have consistently so interpreted Section 101, although there have been occasional, aberrant decisions by individual Patent Office Examiners. Since the decision to issue a patent is not administratively reviewable, these aberrant decisions have resulted in a few instances in the issuance of patents for living organisms.

tion when it enacted the Plant Patent Act (R.S. (35 U.S.C. 161 *et seq.*) in 1930, and when it extended patent-type protection to other varieties of plants in the Plant Variety Protection Act, 7 U.S.C. 2321 *et seq.* in 1970.

The legislative history of both Acts clearly indicates that Congress intended to extend the protections of the patent laws to previously unprotected agricultural inventions. Inanimate inventions relating to agriculture had always been covered by the patent law; the only reason that legislation was required was because the subjects to be newly protected were alive.

Neither the 1930 nor the 1970 Act permits the patenting of naturally occurring plants that have simply been found by their claimed discoverer. Both Acts require that the inventor must, like Chakrabarty, have actually developed the new variety by creating a hybrid form that does not exist in nature. New legislation was necessary to permit the patenting of such newly created plants.¹⁰ That legislation does not encompass Chakrabarty's invention; accordingly, it is not patentable.

¹⁰ As the CCPA noted, patents for processes involving living organisms have long been issued. But that does not suggest that the organisms themselves are patentable, since a process using unpatentable elements or producing an unpatentable end product is patentable so long as the process itself qualifies under the patent law.

ARGUMENT

I. ABSENT A CLEAR CONGRESSIONAL INTENT TO AFFORD PATENT PROTECTION TO LIVING ORGANISMS, THE PATENT STATUTE SHOULD NOT BE INTERPRETED TO EXTEND COVERAGE TO NEW LIFE FORMS

This Court only recently held that the judiciary "must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress." *Parker v. Flook*, 437 U.S. 584, 596 (1978). In such cases, the patent laws will not be held to apply unless there is "a clear and certain signal from Congress", for such an extension makes "the beachhead of [monopoly] privilege * * * wider, and the area of public use narrower * * *." *Id.* at 596. This ruling was a reflection of the general principle that, because of "this Nation's historical antipathy to monopoly", the patent laws are strictly construed. *Deepsouth Packing Company v. Laitram Corp.*, 406 U.S. 518, 530 (1972); see also *Sears, Roebuck & Company v. Stiffel Company*, 376 U.S. 225, 230 (1964); *Graham v. John Deere Company*, 383 U.S. 1, 7 (1966). Strict construction serves a function beyond confining monopoly, moreover. Decisions on whether and how to extend the patent monopoly require policy judgments involving economic and scientific considerations. Congress is the governmental institution that is empowered and best able to make such decisions. *Parker v. Flook*, *supra*, 437 U.S. at 595-596. This proceeding offers a virtual case study justifying the application of those principles.

As the Court of Customs and Patent Appeals readily acknowledged, the question involved is an issue of first impression (Pet. App. 68a). Thus, almost 190 years after the first patent statute was enacted and after numerous amendments to the basic law, the court's decision is the first holding by any court that living organisms are themselves either a "manufacture" or a "composition of matter" and thus patentable. Indeed, until the decision below, it was the general understanding that patent coverage was not available and that legislation was needed if patent protection was to be extended to microorganisms. The only judicial pronouncements on the subject suggested that living things are not themselves patentable. *Guaranty Trust Company v. Union Solvents Corporation*, 54 F.2d 400, 410 (D. Del. 1931), *aff'd*, 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933). The CCPA had itself so indicated. *Application of Mancy*, 499 F.2d 1289, 1294 (C.C.P.A. 1974).¹¹ The Patent, Trademark and Copyright Law

¹¹ The CCPA in *Mancy* "presumed" that the applicants would have been "unable to obtain [an allowed] claim [for a novel strain of *Streptomyces*] because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature.'" *Mancy*, *supra*, 499 F.2d at 1294. In the instant cases the CCPA suggested that this dictum meant only that the claim lacked novelty because the microorganism was "plucked from the earth" (Pet. App. 46a). But the *Mancy* court surely meant the "product of nature" language in a sense broader than simply a thing found in nature, unchanged by the hand of man, for *Mancy*'s production of the antibiotic daunorubicin using *Streptomyces bifurcus* involved a laboratory process of isolation and cultivation of the microorganism in a defined nutrient medium. *Mancy*, *supra*, 499 F.2d at 1290. It was thus like Bergy's

Section of the American Bar Association and its subcommittees repeatedly went on record as favoring new legislation to extend the scope of the patent laws so that various living things, including microorganisms, might at last be patented.¹² Writers

biologically pure culture of *Streptomyces vellosus*, which the same judges who decided *Mancy* found did "not define a product of nature" (Pet. App. 39a).

The issue of living organism patentability was raised, but not decided, in *Application of Merat*, 519 F.2d 1390, 1393 (C.C.P.A. 1975) (claim to a hybrid chicken produced by a specified process).

¹² In 1966, the American Bar Association Patent Section passed Resolution 22 entitled "Extension of Patent System to Biological Arts Not Now Covered" favoring coverage under the patent law for, among other things, "micro-organisms, and animal husbandry." ABA Patent, Trademark and Copyrights Law Section, 1966 *Summary of Proceedings* 59, 74 (1967).

In 1969, Subcommittee E of the ABA Patent Section reported, after studying "articles which advocated the extension of the Plant Patent Act to include micro-organisms," that "[t]here is a growing concern by many that the micro-biological art is ready to enjoy the fruits of the patent system [and that] [t]here is also a growing belief that the micro-biological art needs stimulation of the kind offered by a patent system." ABA Patent, Trademark and Copyright Law Section, 1969 *Committee Reports* 123 (1970).

In 1976 Committee 111 of the ABA Patent Section proposed another Resolution 22, which favored among other things "amendment of 35 U.S.C. 161 [defining the subject matter for plant patents] * * * to render patentable new forms of microorganisms." ABA Patent, Trademark and Copyright Law Section, 1976 *Committee Reports* 110 (1977). The proposed recommendation regarding microorganisms was not approved by the Section, however, apparently because the purpose of the resolution was to come within the pro-

on patent law agreed that a new statute was necessary, and some urged Congress to legislate.¹³

nouncements of a European treaty on plant patent protection (Union for the Protection of Obtentions Vegetal) and "it did not seem 100% essential that protection be given to microorganisms in order to do that." ABA Patent, Trademark and Copyright Law Section, 1976 *Summary of Proceedings* 95 (1977).

Similarly, the American Patent Law Association in 1967 adopted a resolution favoring the extension of the patent laws to "all the agricultural arts (including all plants * * * microorganisms and animal husbandry)." *Patent Law Revision: Hearings on S. 2, S. 1042, S. 1377, S. 1691, S. 2164, S. 2597 Before the Subcomm. on Patents, Trademarks and Copyrights of the Senate Comm. on the Judiciary*, Part 2, 90th Cong., 2d Sess. 549 (1968) (Statement of Eben M. Graves, President, American Patent Law Association). That association recommended the enactment of legislation to accomplish that extension. *Id.* at 546, 553.

¹³ The late John A. Dienner, a past president of the American Patent Law Association and a past Chairman of the ABA Patent Section, reported that in 1928 he conferred with Secretary of Agriculture Hyde, "with a view to providing legislation granting broad protection like that of a patent to all originators of plants and animals and products thereof * * *." Dienner, *Patents for Biological Specimens and Products*, 35 J. Pat. Off. Soc'y 286, 290 (1953). According to Dienner, "Secretary Hyde was enthusiastic, but the movement was kidnaped and disguised as the 1930 Plant Patent Act." *Ibid.* Other experts writing on the subject likewise thought that without additional legislation no patents could issue for living things, other than those plants covered under the Plant Patent Act. See, e.g., Rossman, *The Preparation and Prosecution of Plant Patent Applications*, 17 J. Pat. Off. Soc'y 632 (1935). In that article, former Patent Office Examiner Joseph Rossman argued: "The plant [patent] law should * * * logically be extended to all forms of plants without restriction as to method of reproduction or type. The next step would

Congress has not yet followed these recommendations for legislation. Should it consider doing so, it would be required to determine the scope of the patent protection (if any) to be provided, in light of the difficult and controversial policy questions involved in any extension of patent protection to living things.

The legislature has far more flexibility than the judiciary in making such determinations. It can, for example, decide, as it has done in the Plant Patent Act (35 U.S.C. 161 *et seq.*) and the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*), to extend the patent laws to specifically defined categories of living things. It can also tailor the precise limits of the protections available and the statutory requirements for obtaining those protections to reflect the particular attributes of the forms protected, as it has done in those Acts.¹⁴ See 35 U.S.C. 162, 163; 7 U.S.C. 2404, 2422, 2483(c), 2543, 2544. Cf. *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1379-1383 (5th Cir. 1976), cert. denied, 429 U.S. 1094 (1977); Jeffery, *The Patentability and Infringement of Sport Varieties: Chaos or Clarity?*, 59 J. Pat. Off. Soc'y 645, 654-657 (1977).

be to enact a law for patenting novel types of animal life." *Id.* at 644. And see Glascock and Stringham, *Patent Soliciting and Examining* 591 (1934); R. Allyn, *The First Plant Patents* 10 (1934).

¹⁴ For example, the reproductive ability of living things, and the small likelihood that even the most exact description of the method by which the originator developed his claimed invention will permit its duplication, mean that living things do not fit easily within the general patent statute. See *R. Allyn, supra, passim*.

The courts have much more limited options. Since both the Plant Patent Act and the Plant Variety Protection Act define with some precision the life forms to which they apply (35 U.S.C. 161; 7 U.S.C. 2401, 2402),¹⁵ the only way the courts can extend patent protection to other living organisms is by the route chosen by the CCPA—by concluding that "we do not see * * * any sound reason for making the distinction * * * between the living and the dead" (Pet. App. 65a; emphasis in original), and thus treating living organisms as precisely the same as any subject matter patentable under Section 101.¹⁶

Even if Congress were to limit its consideration of the desirability of extending patent protection to microorganisms, it would have to make difficult policy decisions with far-reaching effects. Chakrabarty's discovery is closely related to recombinant DNA re-

¹⁵ The organisms involved here are not patentable under those Acts. The Plant Variety Protection Act specifically excludes bacteria (7 U.S.C. 2402), and the Plant Patent Act applies only to the "invent[ion] or discover[y] and asexual reproduc[tion of] any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state." 35 U.S.C. 161. See *In re Arzberger*, 112 F.2d 834 (C.C.P.A. 1940).

¹⁶ Even the CCPA recognized elsewhere in its opinion that this "all or nothing" approach was not appropriate in dealing with living organisms, and disavowed any intent to suggest the patentability of life forms other than microorganisms (Pet. App. 45a). It failed, however, to suggest why its conclusion concerning the scope of Section 101 would not also apply to other living organisms, and, indeed, at least implicitly recognized that it would (Pet. App. 48a-49a, 64a-67a).

search¹⁷ and like that research involves "genetic engineering" (Pet. App. 143a).¹⁸

Research in this area is already highly controversial, in part because of the potential hazards involved.¹⁹ Microorganisms with transplanted genes, if allowed to escape into the environment or to infect

¹⁷ DNA (deoxyribonucleic acid) is the basic genetic material that determines the hereditary characteristics of the cell. Using enzymes that can break up designated DNA strands and couple the broken fragments in new combinations, microbiologists have been able to introduce foreign genes into bacteria or into a culture of cells in a test tube. See "Recombinant DNA Research: Guidelines Released by the National Institutes of Health," 41 Fed. Reg. 27902-27941 (1976). The agent (vector) used to effectuate the transfer of the DNA is a plasmid, the cell particle employed by Chakrabarty (Pet. App. 35a), or a virus. 41 Fed. Reg. 27903-27904 (1976). Cells containing recombinant DNA can be bred in a genetically homogeneous culture. Recombinant DNA Research, *Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules," February 1975-June 1976*, 160-162, DHEW Pub. No. (NIH) 76-1138 (National Institutes of Health, Public Health Service (1976). Such cultures, or bacteria carrying the recombinant DNA, have potential for commercial use, for example, in the production of human hormones or organic chemicals, and in increasing the photosynthetic efficiency of plants. *Id.* at 4; Wade, *Recombinant DNA: Warming Up For Big Payoff*, 206 Science 663 (1979).

¹⁸ The CCPA spoke approvingly of the research being conducted by Genentech, Inc., which is attempting to exploit the commercial possibilities of recombinant DNA, and strongly implied that the microorganisms it is creating are patentable (Pet. App. 42a).

¹⁹ Moreover, as amicus Peoples Business Commission points out, there is the possibility that permitting patenting may actually lead to a reduction in the genetic diversity of the life forms involved. Brief 6-12.

laboratory workers and others, could be hazardous to man or to other life forms. See "Recombinant DNA Research: Guidelines Released by the National Institutes of Health," 41 Fed. Reg. 27904 (1976) (hereafter "Guidelines"); Brief on behalf of the Peoples Business Commission, 18-21. It was for this reason that the Director of the National Institutes of Health in 1976 released guidelines for NIH-sponsored research on recombinant DNA that established controlled conditions under which such research was to be performed. 41 Fed. Reg. 27902.²⁰ Continuing controversy over the degree of governmental control of recombinant DNA research²¹ has resulted in revisions of these guidelines.²²

²⁰ Comments were sought prior to the release of the guidelines. While some commentators found the guidelines adequate and others considered them onerous (41 Fed. Reg. 27904 (1976)), the Director reported that still others believed that the hazards posed were unique. *Ibid.* In their view, "the occurrence of an accident or the escape of a vector could initiate an irreversible process, with a potential for creating problems many times greater than those arising from the multitude of genetic recombinations that occur spontaneously in nature." *Ibid.* See 1 Recombinant DNA Research, *supra*, at 65-68, 134-139, 372-401. The guidelines treat the problem of physical isolation of research on recombinant DNA in the laboratory as well as limitations on the use of certain vectors. 41 Fed. Reg. 27904 (1976).

²¹ It was recently reported that Genentech and Eli Lilly have asked NIH for "permission to exceed the 10-liter limit now imposed on the amount of culture allowed in any recombinant DNA process." *Chemical Week* 34 (Sept. 26, 1979). Draft standards for such large scale research are being considered. 44 Fed. Reg. 63074, 63075 (1979).

²² See "Recombinant DNA Research: Revised Guidelines," released by the National Institutes of Health, 43 Fed. Reg.

One aspect of this controversy is the extent, if any, to which patent grants should be afforded on organisms that result from genetic engineering. Some persons believe that the ethical problems raised by creating the genetic material of life—including human life—should not be compounded by providing that such life can be “owned” by patent holders. See Brief on Behalf of Peoples Business Commission, 9-13. Others favor exploitation of this research under the patent system and suggest that the patent system might control public health risks. Yet others are skeptical of this claim and see the need for far more consideration of the relationship between patent law and genetic engineering.²³ Resolution of such disputes is precisely the type of task for which Congress, and not the judiciary, is equipped.

The difficult policy questions raised by extension of patent protection to this vast new field make it

60080, 60108, 60134 (1978). See also “Recombinant DNA: Accelerated Processing of Patent Applications for Inventions,” 42 Fed. Reg. 2712-2713 (1977), which provided for special procedures for processing applications “relating to recombinant DNA, including those that contribute to safety of research in the field” (*ibid.*). This regulation was suspended in part by “Recombinant DNA: Suspension of Accelerated Processing of Patent Applications for Recombinant DNA Research Inventions,” 42 Fed. Reg. 13147 (1977). See also Wade, *Major Relaxation on DNA Rules*, 205 Science 1238 (1979).

²³ See generally the comments submitted to the Director of NIH and collected in 2 Recombinant DNA Research, *Documents Relating To “NIH Guidelines For Research Involving Recombinant DNA Molecules,”* June 1976-November 1977, 3-17 DHEW Pub. No. (NIH) 78-1139 (National Institutes of Health, Public Health Service, 1978).

incumbent on the judiciary to proceed with great caution. As this Court held in *Parker v. Flook*, judicial approval of the extension of patent coverage to a new field requires “a clear and certain signal from Congress.” 437 U.S. at 596. The Court in *Flook* found no such signal to allow extension of patent coverage to the “modern business of developing programs for computers.” *Id.* at 595. The ethical, health, and economic problems posed by granting patent protection to living things are, if anything, more vexing than those posed by computer programs. And, as we shall now show, not only has there been no “clear and certain signal” from Congress authorizing patent coverage, there are persuasive indications that Congress has never intended to authorize the patentability of microorganisms or living things generally under 35 U.S.C. 101.

II. CONGRESS DID NOT INTEND TO INCLUDE LIVING THINGS THEMSELVES WITHIN THE SCOPE OF THE GENERAL PATENT LAWS

The text of the patent statutes reflects a congressional intent that living things themselves are not patentable under Section 101. That Section provides that a patent may issue to the inventor of a new and useful “manufacture, or composition of matter.” Sections 161-164 of the Patent Code expressly authorize the grant of patents on one carefully defined class of living things. These Sections, passed in 1930 as an amendment to the predecessor of Section 101 and known as the Plant Patent Act, afford patent protection to certain kinds of asexually-reproduced plants.

As thus amended by the Plant Patent Act, Rev. Stat. 4886, the predecessor of Section 101, read in pertinent part:

Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof, or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant, * * * may * * * obtain a patent therefor.

The very fact that Congress originally added these provisions to the predecessor of Section 101 strongly indicates a congressional understanding that the terms "manufacture, or composition of matter" did not extend to living things, for otherwise the new authorization for issuance of a patent to one "who has invented or discovered and asexually reproduced any distinct and new variety of plant * * *" would have been redundant (and perhaps would have had the effect of repealing patent authorization for other types of plants, although Congress treated the Act as an extension, rather than a contraction, of patent coverage).

Similarly, the Plant Variety Protection Act, 7 U.S.C. 2402(a), enacted in 1970, enlarged the class of protectable living things by authorizing patent-type protection for new types of sexually reproduced plants. This Act, too, would be redundant under the reading of Section 101 adopted by the court below, for under that reading living things already were

patentable as "manufacture[s], or composition[s] of matter." See *Platt v. Union Pacific R.R.*, 99 U.S. 48, 58 (1878); *Born v. Allen*, 291 F.2d 345, 351 (D.C. Cir. 1960). See also *United States v. Ruzicka*, 329 U.S. 287, 293 (1946). These specific and carefully delimited amendments—which the decision below would either render meaningless or contort into partial repealers of a comprehensive authorization for patents on living things²⁴—are thus strong evidence that the general subject matter definition in Section 101 does not include living things.²⁵ Cf. *Stonite Products Co. v. Melvin Lloyd Co.*, 315 U.S. 561 (1942); *Fourco Glass Co. v. Transmirra Corp.*, 353 U.S. 222, 228 (1957).²⁶

The legislative history of the plant patent statutes confirms this reading. Congress in the Plant Patent Act intended to extend patent protection for the first

²⁴ Indeed, the Plant Variety Protection Act provides more limited protection than the general patent law in several respects. Compare 35 U.S.C. 271 with 7 U.S.C. 2541; cf. 7 U.S.C. 2543 (farmers may save seed from plants grown from protected seeds for replanting or sale to other farmers).

²⁵ Similarly, designs are not included within the general definition of patentable subject matter in Section 101, but are specifically provided for in 35 U.S.C. 171.

²⁶ Judge Baldwin's concurrence focuses on the scope of the claims involved, and concludes that they define statutory subject matter because they do not seek to "preempt natural laws or phenomena" (Pet. App. 73a, 91a). But this analysis overlooks the fact that, regardless of the scope of the claims, the subject matter involved is a living organism—simply not the kind of discovery that the statute was designed to protect. Cf. *Flook*, *supra*, 437 U.S. at 592-593.

time beyond its previous limits. See *Application of Le Grice*, 301 F.2d 929, 939 (C.C.P.A. 1962). Both the House and Senate committees considering the bill reported that:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry * * *. The bill will remove the existing discrimination between plant developers and industrial inventors. [H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930)].²⁷

Appended to both the House and Senate Reports were letters from then Secretary of Agriculture Hyde, solicited by the respective committee chairmen, referring more specifically to the coverage of the pre-existing patent law:

The evident purpose of the bill is to encourage the improvement of some kinds of cultivated plants * * *. This purpose is sought to be accom-

²⁷ The theme that plant developers did not have the benefits of the patent system appears throughout the committee reports. Both the House and Senate reports pointed out that, "[t]o-day the plant breeder has no adequate financial incentive to enter upon his work. A new variety once it has left the hands of the breeder may be reproduced in unlimited quantity by all." H.R. Rep. No. 1129, *supra*, at 1; S. Rep. No. 315, *supra*, at 1. The Committees also noted that "there is no apparent difference * * * between the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter which are patentable under existing law." H.R. Rep. No. 1129, *supra*, at 7; S. Rep. No. 315, *supra*, at 7.

plished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inanimate nature. [H.R. Rep. No. 1129, *supra*, at Appendix A; S. Rep. No. 315, *supra*, at Appendix A.]

The Secretary's opinion on the existing law's scope, considered by Congress when it passed the Plant Patent Act, is entitled to substantial weight in statutory construction. See *New York Central R.R. v. Winfield*, 244 U.S. 147, 149-150 (1917); *United States v. Silk*, 331 U.S. 704, 710 n. 5 (1947); *Johnson v. Southern Pacific Co.*, 196 U.S. 1, 19-20 (1904). That weight is all the greater since Congress valued the Secretary's views on the need for new legislation and charged him with an important role in its administration. See H.R. Rep. No. 1129, *supra*, at 3; S. Rep. No. 315, *supra*, at 3.²⁸

²⁸ Thus the CCPA's disregard of Secretary Hyde's opinion concerning existing law, because Congress asked for his views only "on the proposed participation of his department in the *administration* of the new law" (Pet. App. 62a; emphasis in original) is wide of the mark. The court further erred in stating that "[t]here is no reason to attribute it [the Secretary's opinion] to Congress" (*ibid.*). The committees plainly found the Secretary's views significant; while they did not discuss in the committee reports his opinion on the existing law's subject matter coverage, they both referred to his letter in connection with other matters. H.R. Rep. No. 1129, *supra*, at 3, 6; S. Rep. No. 315, *supra*, at 3, 5. In view of their respect for the Secretary's interpretation of the proposed bill, and the fact that his understanding of the scope of existing law was nowhere challenged in the reports, the committees' failure to discuss his letter on the issue of coverage strongly indicates general agreement with his views

The principal House sponsor of the bill, Representative Purnell, held similar views. During House hearings, he concurred in the hope "that some day the patent law would be amended so as to give the man who developed new forms of plant or animal life an opportunity to control reproduction." *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 4 (1930).²⁹ Representative Purnell was confident that to amend the law to allow patents on living things would benefit the public. Some legislators did not share Purnell's optimism, but even opponents agreed that the new law provided patentability for living things that was not available under existing law. See, e.g., 72 Cong. Rec. 8391 (1930) (remarks of Rep. Stafford).³⁰

on the issue—especially since similar views are stated in the committee reports themselves (see n.27, *supra*).

Respondent Chakrabarty suggests that the Secretary's views should be disregarded because he was "not shown to have any expertise in the patent law" (Brief in Opposition 11). This comment assumes that the letter was written without consultation, which would be at least unusual for the formal expression of a federal department's views on pending legislation in a field of mutual concern to several departments. In any event, the Secretary had the advice of expert patent counsel, before writing his letter. See *Diener*, *supra*, note 13.

²⁹ The opinion was stated in what Rep. Purnell called a "splendid" letter containing the views of Chicago patent attorney, Col. Francis W. Parker, who had studied this issue. *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 4 (1930).

³⁰ Rep. Stafford at the beginning of House debate on the bill objected that the bill "is establishing a precedent to provide for a patent to those who develop a rare species of cattle or chickens." 72 Cong. Rec. 8391 (1930).

In 1970 Congress again evidenced its belief that living organisms were not covered by 35 U.S.C. 101, and that to afford them protection separate legislation was needed. The Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542, 7 U.S.C. 2321 *et seq.*, gave the Secretary of Agriculture authority to issue certificates of Plant Variety Protection, similar to patents, for new varieties of sexually-reproduced plants (Section 51, 7 U.S.C. 2421).³¹ Significantly, the statute expressly provides that bacteria are not entitled to plant variety protection (Section 42, 7 U.S.C. 2402). The legislative history does not explain the reason for this exclusion,³² but it cannot fairly be read as supporting the conclusion that the exemption was intended to preserve an assumed pre-existing patentability of bacteria under the general patent law.³³

³¹ The objection to including sexually reproduced plants under the 1930 Plant Patent Act had been that new varieties could never be reproduced true-to-type through seedlings. S. Rep. No. 315, *supra*, at 4; H.R. No. 1129, *supra*, at 4-5. But by 1970 it was generally recognized that new seed plant varieties could sometimes be reproduced true-to-type. See ABA Patent, Trademark and Copyright Law Section, 1968 *Committee Reports* 29 (1969).

³² As the court below suggested (Pet. App. 63a), the exclusion may simply have reflected congressional agreement with the result reached in *In re Arzberger*, 112 F.2d 834, 837 (C.C.P.A. 1940), in which the CCPA had recognized that "the characteristics of plants predominate in bacteria, and bacteria are usually scientifically classified as plants," but nevertheless affirmed the Board's refusal to issue a plant patent for certain bacteria.

³³ Nothing in *Arzberger* implies that the bacteria could have been patented under the general patent law. Instead, the court

Instead, the legislative history of the Plant Variety Protection Act unmistakably indicates that Congress was extending protection to articles not previously covered under the patent laws—*i.e.*, articles that were not within the terms of either the 1930 Act or 35 U.S.C. 101.³⁴ Thus, the House Report states (H.R. Rep. No. 91-1605, 91st Cong., 2d Sess. 1 (1970)):

Under patent law, protection is presently limited to those varieties of plants which reproduce asexually * * *. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans.

A similar statement appears in the Senate report, S. Rep. No. 91-1246, 91st Cong., 2d Sess. 3 (1970). Lack of coverage under the patent law for sexually reproduced plants was specifically brought to the Congress' attention by the Act's sponsors in the Senate and by the chairman of the Committee on Agriculture in the House during the debates on the bill. 116

quoted with approval the examiner's statement that the Plant Patent Act was not designed "to afford patent protection for bacteria" (112 F.2d at 836), suggesting that no such protection was otherwise available.

³⁴ Since the Plant Variety Protection Act covers similar subject matter, and indeed is fashioned after the Plant Patent Act, it must be construed together with the general patent laws. See *Northcross v. Memphis Board of Education*, 412 U.S. 427, 428 (1973); *Allen v. Grand Central Aircraft Co.*, 347 U.S. 535, 541 (1954).

Cong. Rec. 34680 (1970); 116 Cong. Rec. 40295 (1970). The same theme was repeatedly echoed by seed manufacturers, patent lawyers,³⁵ government officials, and congressmen during the hearings on the bill. *Plant Variety Protection: Hearings on H.R. 13424, etc., Before the Subcomm. on Departmental Operations of the House Comm. on Agriculture*, 91st Cong., 2d Sess. 6, 9, 21, 24, 25, 30, 33, 40, 43-44, 47, 51, 53 (1970). *Plant Variety Protection Act: Hearings on S. 3070 Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture and Forestry*, 91st Cong., 2d Sess. 48, 50, 68, 69 (1970). Moreover, the Act exempts "okra, celery, peppers, tomatoes, carrots, and cucumbers." 7 U.S.C. 2583. The reason for the exemption was that since food processing companies, the major developers of these plants, "do not produce new varieties for sale as such" there would be no purpose in affording them protection. S. Rep. 91-1246, *supra*, at 2. This rationale evidently assumes

³⁵ The resolutions passed by the ABA Patent Section favoring extension of the basic patent laws to cover sexually reproduced plants and microorganisms (see note 12, *supra*) are summarized in the testimony of Andrew Klein before the House Agriculture Committee. *Plant Variety Protection: Hearings on H.R. 13424, etc., Before the Subcomm. on Departmental Operations of the House Comm. on Agriculture*, 91st Cong., 2d Sess. 43 (1970). He noted, in both his oral and written presentation, that the ABA had supported one or more bills proposed by Senator McClellan (the chairman of the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee), "with respect to patent protection for micro-organisms" (*id.* at 43, 47). No hearings were held on the bills referred to by Mr. Klein.

these plants are not protected under the general patent laws.

The Court of Customs and Patent Appeals initially tried to avoid this legislative history. Its principal argument was that the history recited above should be ignored, for it "ascribe[s] to a preceding Congress an intent that the members of that Congress did not themselves state" (Pet. App. 51a). This notion that subsequent legislative history should be considered wholly irrelevant finds no support in the decisions of this Court. Careful use of such legislative history is always in order.³⁶

The views of the Congresses that amended Section 101 with the Plant Patent Act and added the Plant Variety Protection Act are particularly useful in discerning the scope of Section 101 for several reasons. They illuminate the meaning of the obscure but key words "manufacture, or composition of matter," terms which hardly define themselves. *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-381 (1969); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 274-275 (1974); *Califano v. Sanders*, 430 U.S. 99, 105-107 (1977). In addition, this legislative history was available to the Congress which in 1952 codified the patent laws in Title 35. Although the 1952 Congress

³⁶ In the primary case cited by the lower court (Pet. App. 51a) to support its disregard of legislative history, *United States v. Price*, 361 U.S. 304 (1960), this Court actually relied in part on subsequent legislative history to interpret a statute. *Id.* at 312-313. The Court simply refused to make inferences from that subsequent legislative history for which there was no basis. *Id.* at 313.

transferred the language covering plant patents from the general patent law (Rev. Stat. 4886, now 35 U.S.C. 101) to a separate section (35 U.S.C. 161 *et seq.*), thus directing its attention specifically to the plant provisions, it made no substantive changes in those provisions, nor any relevant changes in the scope of the general definition of patentable subject matter. Accordingly, the re-enactment of both the general definition and the specific extension constituted a ratification of the interpretation of the relation between those provisions reflected in the Plant Patent Act. The 1952 codification thus confirms that Congress intended to allow coverage for living things only as expressly provided under the Plant Patent Act. See *Douglas v. Seacoast Products, Inc.*, 431 U.S. 265, 278-279 (1977). Finally, as is implicit in the CCPA's failure to cite any other legislative history, this legislative history is the best, and only pertinent, history available—it was only on these occasions that Congress specifically focused on the question of the patentability of living things.

The lower court ultimately did consider the legislative history, and it offered two principal arguments in an effort to explain it away (Pet. App. 56a-61a). First it stated that Congress did not think it important that plants were alive, but only that they were within an agricultural (non-industrial) "field of endeavor" that required stimulation from the patent system (Pet. App. 56-59a). But the patent system from its beginning has been applied to inani-

mate invention in the field of agriculture.³⁷ What distinguishes newly created plants from agricultural machinery is that plants are alive.³⁸ This fact was recognized by both congressional committees considering the Plant Patent Act when they reported that:

There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful natural mineral. [H.R. Rep. No. 1129, *supra*, at 7; S. Rep. No. 315, *supra*, at 6.]

³⁷ See, e.g., *The Corn-Planter Patent*, 23 Wall. (90 U.S.) 181 (1874); *Acme Hay Harvesting Co. v. Martin*, 33 F. 249, 251 (Cir. Ct. N.D. Ill. 1888).

³⁸ This view was shared by many botanists and horticulturalists. Thus, David Fairchild, president of the American Genetic Association, wrote of his work creating new hybrid fruit:

The hybrid is made; let it take its course. It shall have to, since the Patent Laws of America will give me no assistance. Were they fair and designed to support invention in other fields than in those of mechanical things * * * I might awake some day, as inventors have, to find myself drawing a royalty from my Actinidia hybrid.

Fairchild, *The Fascination of Making A Plant Hybrid*, 18 J. of Heredity 49, 62 (1927). And Luther Burbank is quoted as having advocated patent law coverage for new plant varieties, as follows (72 Cong. Rec. 8392 (1930)):

* * * A man can patent a mousetrap or copyright a nasty song, but if he gives the world a new fruit that will add millions to the value of earth's annual harvests, he will be fortunate if he is rewarded by so much as having his name connected with the result * * *

See also Mole, *The Expanding Scientific Role of the Federal Government in the Nineteenth Century: The Patent Office As A Case Study*, 60 J. Pat. Off. Soc'y 328, 331-333, 340-341 (1978).

The CCPA also suggested that in 1930 Congress considered that plants were not patentable because they were thought to be a product of nature "unaffected by the hand of man," not because they were alive (Pet. App. 59a-60a).³⁹ This proposition overlooks the fact that Congress in the Plant Patent Act carefully distinguished between products of nature—plants found in their wild state and then cultivated—and products of man (aided, of course, by nature)—new plant varieties developed by experimenters like Luther Burbank through cross-pollination—and provided patent protection only to certain of the latter.⁴⁰

³⁹ Whatever the merits of this argument as applied to the 1930 Act, it clearly does not explain the 1970 Act. By 1970 numerous new plant varieties had been created using chemicals or radiation to change the genetic structure of naturally occurring plants. See, J. James, *Create New Flowers And Plants Indoors And Out* 116-117, 127-136 (1964); Emsweller, *Use of Colchicine in Plant Breeding*, in Brooklyn Botanic Garden, *Handbook on Breeding Ornamental Plants* 96-97 (1959); Singleton, et al., *Radiation Genetics and Crop Improvement*, in Brooklyn Botanic Garden, *supra*, at 98-100. These varieties are no more "products of nature" than is Chakrabarty's microorganism.

⁴⁰ Burbank's main work involved the production of new plant varieties by cross-pollination or hybridization. H. de Vries, *Plant-Breeding* 174 (1907); D. Jordan & V. Kellogg, *The Scientific Aspects Of Luther Burbank's Work* 4-7 (1909). This involved combining the desirable qualities of different strains within a species, or of different species, and the elimination of undesirable characteristics. De Vries, *supra*, at 174, 210. Burbank's method involved the deliberate transferring of the pollen from the flower of one plant to the stigma of the flower of another plant. W. S. Harwood, *New Creations in Plant Life* 25, 232-233 (1905). Burbank selected the best of the new plants resulting from a number of these crosses and

Thus Congress ultimately accepted the view that plants that are products of nature should remain unpatentable, and enacted the statute solely to extend patent protection to plants that are *not* products of nature, but had, theretofore, nevertheless been unpatentable solely because they are alive.

The plant legislation as originally introduced went so far as to cover even varieties of plants found in nature and then asexually reproduced.⁴¹ The Com-

propagated them. *De Vries, supra*, at 174. Burbank's was not the only work in plant genetics and breeding. X-rays had been used to change the genetic structure of barley and maize seeds prior to passage of the Plant Patent Act of 1930. See Singleton, *et al.*, *Radiation Genetics and Crop Improvement* in Brooklyn Botanic Garden, *Handbook On Breeding Ornamental Plants* 98 (1959). And as early as 1904 one researcher reported doubling chromosomes in plant roots using narcotics. Blakeslee and Avery, *Methods of Inducing Doubling of Chromosomes in Plants*, 28 J. of Heredity 393, 394 (1937). The discussion in the 1930 committee reports demonstrates that Congress was aware of the details of Burbank's work as well as of other research involving the creation of new plant varieties. H.R. Rep. No. 1129, *supra*, at 8; S. Rep. No. 315, *supra*, at 7. While Chakrabarty's research design and equipment is far more sophisticated, in concept the work of these early researchers is not different from Chakrabarty's (see Pet. App. 31a). The bacteria claimed by Chakrabarty are basically hybrid organisms.

⁴¹ The first Senate and House bills, which extended patent protection to "[a]ny person who has invented or discovered * * * any new and distinct variety of asexually reproduced plant," both contained the following proviso:

Provided: That the words "invented" and "discovered" * * * in regard to asexually reproduced plants, shall be interpreted to include invention and discovery in the sense of finding a thing already existing and reproducing

missioner of Patents opposed coverage of this kind of plant, but did support amending the predecessor of Section 101 to allow patents on plants that are the creation of man, not of nature. See *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 6 (1930). Such plants resulted, as he stated, "from human efforts", not from nature, but "the present patent law does not make it possible to grant patents" for them. *Id.* at 6. Congress agreed to this change; for the first time it made a limited class of living things patentable, but only where they were the product of man.

The lower court focused largely on a single decision and law review article antedating the Plant Patent Act: *Ex Parte Latimer*, 1889 Dec. Comm. Pat. 123, and Thorne, *Relation Of Patent Law To Natural Products*, 6 J. Pat. Off. Soc'y 23 (1923) (Pet. App. 59a-60a). The short answer to this constructed legislative history is that the actual legislative history of the Plant Patent Act contains no evidence of congressional awareness of either *Latimer* or the Thorne article: neither is mentioned, let alone relied on. Even if Congress had been aware of them, however, there is nothing in either that suggests that new plant varieties of the type created by Burbank through cross-pollination should be treated as "products of nature". In *Ex Parte Latimer* the Commissioner refused a

the same as well as in the sense of creating. [S. 3530, 71st Cong., 2d Sess., amending Rev. Stat. 4886 (1930); H.R. 9765, 71st Cong., 2d Sess., amending Rev. Stat. 4886 (1930); R. Allyn, *The First Plant Patents* 60 (1934).]

patent on natural fiber taken from the needle of a tree (*Pinus australis*), the extraction of which "natural product" involved "little more than one who gathers the pebbles along the seashore, where the forces of nature have placed them." Dec. Comm. Pat. at 126-127. The decision hardly can be said to imply that new plant varieties created by plant breeders are unpatentable because they are products of nature. Thorne, relying mostly on *Latimer*, confines his "product of nature" discussion to plants "discovered and propagated by scientific means" without saying whether this "discovery" is limited to finding a new plant growing in nature or includes varieties created by horticulturalists. See Thorne, *supra*, at 23; also *id.* at 25, 27-28.

Finally, the court below cited as a reason for passage of the Plant Patent Act the need to overcome the difficulty of describing a plant in a written document (Pet. App. 62a). But while this theory explains the amendment (now 35 U.S.C. 162) to Section 4888 of the Revised Statutes (now 35 U.S.C. 112),⁴² which requires a written description of the invention, it does not explain why Congress found it necessary also

⁴² The amendment read as follows:

Section 4888 of the Revised Statutes, as amended (U.S.C. title 35, sec. 33), is amended by adding at the end thereof the following sentence: "No plant patent shall be declared invalid on the ground of noncompliance with this section if the description is made as complete as is reasonably possible."

to amend Rev. Stat. 4886 (now 35 U.S.C. 101) to include asexually reproduced plants as patentable subject matter. Moreover, difficulty of description was not mentioned in either the House or Senate report as a reason for passing the bill. See H.R. Rep. No. 1129, *supra*, at 1-4; S. Rep. No. 315, *supra*, at 1-3.⁴³

There is, in sum, no plausible indication in the legislative history of any basis for enactment of the Plant Patent Act independent of the repeatedly suggested premise that existing patent law did not authorize the patenting of living things.

III. THE OTHER REASONS OFFERED BY THE COURT BELOW IN SUPPORT OF ITS DECISION ARE UNPERSUASIVE

The court below stated that Congress could not rationally have intended to prohibit the patenting of living things since patents have long been allowed on processes that use living things (Pet. App. 48a-49a; 67a-68a). See *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453, 455-456 (2d Cir.), cert. denied, 209 U.S. 548 (1908); *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628, 630-631, (S.D.

⁴³ The only place in the legislative history where the point was discussed was in the memorandum of Commissioner Robertson in the record of the House hearings. See *Hearings on H.R. 11372, supra*, at 7. It was there mentioned not as a reason for passing the bill, but because the Commissioner thought that if the patent law was amended to make plants patentable subject matter, a further amendment would be needed to relieve plant inventors of the strict specification requirements of Rev. Stat. 4888. *Ibid.*

N.Y. 1930); *Guaranty Trust Company v. Union Solvent Corporation*, 54 F.2d 400 (D.Del. 1931). But it hardly follows that because a process is patentable, every component of that process also qualifies for a patent. Thus, a new and useful process using common, inanimate components in an original way may qualify for a patent without each of those inanimate components themselves being patentable. Compare *Application of Deutsch*, 553 F.2d 689, 692-693 (C.C.P.A. 1977), with *Application of Waldbaum*, 559 F.2d 611, 616-617 (C.C.P.A. 1977). Similarly, a scientific principle or formula, itself not patentable, may provide the theoretical basis for a patentable process. See *Parker v. Flook*, *supra*, 437 U.S. at 591; *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1939). Accordingly, the fact that a patent is allowed on a new and useful process incorporating a living organism does not suggest that the organism itself is patentable subject matter.⁴⁴ Similarly, a method of achieving an unpatentable end product may be patentable. See *Application of Toma*, 575 F.2d 872 (C.C.P.A. 1978) (method of using computer to translate text from one language to another).

The CCPA also stated that the Patent Office has regularly granted patents on living things and

⁴⁴ The court's related proposition that living things are useful, are based on chemistry and thus should receive patent protection (Pet. App. 44a) is no more persuasive. Utility does not mean patentability. *Parker v. Flook*, *supra*. And whether or not life is, as the CCPA would have it, "largely chemistry" (Pet. App. 44a), the decision to extend the patent laws from the nonliving to the living is a policy judgment for Congress to make (see *supra*, pages 12-21).

that administrative practice supports the court's reading of Section 101 (Pet. App. 65a-67a). The policy of the Patent Office, however, is that living things are not themselves patentable, and neither the Commissioner nor the Board of Appeals has deviated from that policy. The court merely cited patents granted by some of the Patent Office's roughly one thousand examiners⁴⁵ that the court asserts were issued on living things (Pet. App. 66a-67a).⁴⁶ These grants have minimal precedential significance, since they were only isolated actions of lower level employees, made on applications neither contested nor reviewed. See *Fishgold v. Sullivan Drydock & Repair Corp.*, 328 U.S. 275, 290 (1946); *SEC v. Sterling Precision Corp.*, 393 F.2d 214, 220 (2d Cir. 1968) (Friendly, J.). Moreover, there is no evidence whatever that Congress was aware of these patents or that the examiners who approved them took part in the legis-

⁴⁵ The Patent and Trademark Office granted 70,320 patents in FY 1978. A staff of 1,064 professional employees worked there at the time, mostly in the patent examining corps. *Commissioner Of Patents And Trademarks, Annual Report FY 1978*, 12, 30 (1979).

⁴⁶ Some of the patents cited by the court claim a virus, which some scientists consider to be without life (Pet. App. 66a-67a, Nos. 5, 8). See Weaver, *The Cancer Puzzle*, 150 Nat'l Geographic 396, 397 (Sept. 1976); Gore, *The Awesome Worlds Within a Cell*, 150 Nat'l Geographic 355, 386 (Sept. 1976). With respect to others the invention apparently resides in nonliving material which is a part of the claim (see Pet. App. 66a, No. 4; 67a, No. 8). One other involves bird seed that is treated at such a high temperature (170-180° F) that the seed is likely dead (Pet. App. 66a, No. 6).

lative process of amendment or codification of the patent laws. See *Helvering v. Hallock*, 309 U.S. 106, 120 (1940); *Zuber v. Allen*, 396 U.S. 168, 192-193 (1969).⁴⁷ The court thus erred in relying on these few aberrant patent grants by individual examiners as persuasive evidence of administrative interpretation of the patent laws, rather than relying on the Commissioner's considered interpretation of the statute he is charged with administering. *Udall v. Tallman*, 380 U.S. 1, 4 (1965).⁴⁸

⁴⁷ The sole possible exception is the 1873 Pasteur patent on yeast (Pet. App. 65a), which P. J. Federico, a principal draftsman of the Patent Act of 1952 (*id.* at 42a n.11), had noted was unique as to subject matter and probably wrong. Federico, *Louis Pasteur's Patents*, 86 Science 327 (1937).

⁴⁸ The CCPA also noted as a "matter of general interest" that the assignee of Chakrabarty's invention had been granted a British patent on the microorganism itself (Pet. App. 33a n.9). We have been advised by the British Patent Office that the claim was granted by the examiner there, but was not reviewed by the appeals board or by higher authority and was not subsequently challenged. We are further advised that the present practice on the granting of such patents in England is uncertain. See, e.g., *American Cyanamid Company (Dann's) Patent*, 1971 Pat. Cas. 425, 448 (Lords), where Lord Wilberforce commented: "The priceless strain, being something living, found in nature, cannot be patented * * *." In any event, it is settled that foreign practice has no bearing on the interpretation of the United States patent law. See *Application of Larsen*, 292 F.2d 531 (C.C.P.A. 1961), and cases cited therein.

CONCLUSION

For the foregoing reasons, the judgments of the Court of Customs and Patent Appeals should be reversed.

Respectfully submitted.

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